REMARKS

An Office Action was mailed in the above-captioned application on September 29, 2004. In such Office Action claims 1-78 were pending. Claims 1-30, 37-44, 51, 52, and 54-78 were withdrawn from consideration. Claims 31-36, 45-50, and 53 were rejected. This Amendment and Remarks document is submitted in response to said Office Action.

Restriction Requirement

The previous restriction requirement has been made final. Claims 1-30, 37-44, 51, 52, and 54-78 have been cancelled as being directed to a non-elected invention. Applicant reserves the right to prosecute the cancelled subject matter in a continuing application. New claim 79, directed to a use for EG307 polynucleotides of the present invention, has been added.

Title/Specification

The title of the invention has been objected to as not being descriptive. By the foregoing amendment, the title of the invention has been amended to read: EG307 POLYNUCLEOTIDES AND USES THEREOF. As requested by the Examiner, the paragraph containing continuing information has been updated.

The Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 31-36, 45-50, and 53 under 35 U.S.C. § 112, second paragraph. The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area which applicants regard as their invention with a *reasonable* degree of precision and particularity.

The rejection indicates that the claims are unclear as it cannot be determined what is encompassed by and "EG307" polynucleotide or polypeptide. The claims have been amended to recite specific EG307 polynucleotides and polypeptides with reference to the SEQ ID NO:'s disclosed in the specification, and to refer to the function of the polynucleotides and polypeptides as yield-related and conferring substantially the same yield as the identified polypeptides. In particular, the claims now recite EG307 polynucleotide sequences SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO: 91, SEQ ID NO:33, SEQ ID NO:34, and SEQ ID NO:35, and EG307 polypeptide

sequences SEQ ID NO:6 and SEQ ID NO:36. Applicant notes that nucleotide sequences SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO: 91 encode the same protein (SEQ ID NO:6) (see page 39, lines 12-27), they are not considered to be independent and distinct inventions and should be examined together (MPEP § 803.04). SEQ ID NO:33, SEQ ID NO:34, and SEQ ID NO:35 also encode the same protein (SEQ ID NO:36), and therefore should also be examined together. Furthermore, EG307 polynucleotide sequences SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO: 91, SEQ ID NO:33, SEQ ID NO:34, and SEQ ID NO:35 have 84% sequence identity overall; and EG307 polypeptide sequences SEQ ID NO:6 and SEQ ID NO:36 have about 94% sequence identity overall. Due to the high sequence similarity, Applicants submit, therefore, that the search for these sequences does not constitute a serious undue burden on the Examiner, and that all EG307 sequences should be examined together (MPEP § 803).

The rejection indicates that claim 34 is confusing because "the EG307 gene" lacks proper antecedent basis. Claim 34 has been amended to recite "an EG307 gene."

The rejection indicates that claim 35 is confusing because of the language "recombinant polynucleotide." Applicants assert that the meaning of this term is self-evident. A polynucleotide is a "polymeric compound, usually DNA or RNA, consisting of a number of nucleotides." (See, *The American Heritage® Dictionary of the English Language, Fourth Edition.*) Recombinant means "formed by or showing recombination," or "of or relating to recombinant DNA." (*Id.*) Recombination, in turn is "the process of 'shuffling' of genes by which new combinations can be generated." Recombination can be accomplished by numerous means. (See The Columbia Electronic Encyclopedia, Sixth Edition).

The rejection indicates that claim 36 is confusing because it is drawn to a method, but depends from "polynucleotide" claim 34. Claim 36 has been amended to refer to the polynucleotide of claim 34.

The rejection indicates that claim 47 is confusing because of the language "encoding and EG307 gene." This language has been removed from Claim 47.

Reconsideration is respectfully requested.

The Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 31-36, 45-50, and 53 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the art the inventors, at the time the application was filed, had possession of the claimed invention.

The first paragraph of § 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971). Further, a specification "may be enabling even though some experimentation is necessary," *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not "undue experimentation." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is whether the specification "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Further, it is a tenet of patent law that an applicant need not teach what the skilled artisan already knows. Instead, it is preferred that an applicant "omit what is known in the art." *Hybritech Inc. v. Monoclonal Antibodies*, 231 USPQ 81, 94 (Fed. Cir. 1986). It is incumbent on the Patent Office "to back up assertions of its own with acceptable evidence or reasoning . . . ." *In re Marzocchi* 169 USPQ at 370. Each member of a Markush group should be specifically contemplated in the Specification and the Markush group should be supported by a generic teaching and examples which teach how to prepare those members whose preparation is not specifically disclosed. *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971). With this standard in mind, the rejections raised by the Examiner are discussed below.

Claim 48 has been rejected as being drawn to a hypothetical agent, which might be identified by the method of claim 46. Claim 48 has been cancelled.

Claims 31-36, 45-50, and 53 have been rejected as lacking written description for the genus of polynucleotides and polypeptides referred to as "EG307." Regarding the statement that it is unclear what is included in the genus of "EG307" polypeptides/polynucleotides, applicant submits that the amendments to the claims as described above have clarified the EG307 genus. The rejection indicates that the proper inquiry in the instant situation is: is there a representative number of species implicitly or explicitly disclosed, such that one of ordinary skill in the art would understand applicant to be in possession of the claimed genus? The rejection indicates that even if it were assumed that the genus contains all plant polypeptides/polynucleotides

having a certain degree of sequence identity with disclosed polypeptides/polynucleotides having specific SEQ ID NOS, and it is considered that several species within this genus are disclosed in the specification, the written description requirement for the claimed genus is not satisfied. The rejection reasons that with the exception of the disclosed SEQ ID NOS, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation.

Applicant respectfully traverses this rejection. The reasoning of the rejection does not take into account the disclosure provided in the specification. Furthermore, the case citations upon which the rejections relies describe fact patterns which are distinguishable from the present application. *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 recite that "[a]dequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required." This is distinguishable from the present case, as numerous nucleic acid sequences are provided, as well as the actual methods for isolating them. Similarly, in *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (BPAI 1993), the disclosure of one bovine sequence lacked written description for the broad class. In the present application, however, numerous sequences from various organisms are provided. *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) is similarly distinguishable. The cited passage states that "[n]o sequence information indicating which nucleotides constitute human cDNA appears in the patent;" however, in the present case, numerous example of EG307 polynucleotides are provided. *University of California* makes reference to "no distinguishing information concerning [the cDNAs] identity," and "no further information . . . pertaining to that cDNA's relevant structural or physical characteristics." Again, this is distinguishable from the present case, as detailed information concerning the identity, and relevant structural and physical characteristics of EG307 polynucleotides and peptides are provided in the instant specification, as explained in detail below.

The rejection asserts that species specifically disclosed are not representative of the genus because the genus is highly variant, encompassing related nucleic acids with potentially different functions/properties, such as encoding polypeptides with different properties, or providing hybridization probes of different specificities among a range of different target organisms. Applicant submits that the claims, as amended, address these concerns and fully satisfy the

written description requirement. The pending claims refer to the use of a genus of polypeptides and polynucleotides related to (i.e., bearing structural and functional similarity to) the *O. sativa* polypeptide of about 447 represented by SEQ ID NO: 6, or the *O. sativa* polynucleotide represented by SEQ ID NO: 4 (specification, page 32-33). The rejections appears to argue that while species claims may be enabled, the genus claim is not. For each claim drawn to a genus, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species which are adequately described are representative of the entire genus. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. *See* The Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (January 5, 2001) [hereinafter Written Description Guidelines]. Here, the skill and knowledge in the art is high as evidenced by the section of the specification entitled "General Procedures known in the art," at page 18, the number of commercially available tools for isolation of polynucleotides and polypeptides as described in the EXAMPLES section, and throughout the disclosure. Thus, the representative number of species needed to meet the written description requirement is minimal.

In the present case, Applicant has demonstrated the existence and identification of EG307 polynucleotides from numerous rice and corn species and ancestors. Example 10 describes the discovery of the EG307 gene in rice, and Example 13 describes the identification of EG307 in maize and teosinte using the rice EG307 sequences. The EG307 polynucleotides have been identified from several strains and cultivars of *O. sativa,* including Azucena, Nipponbare Teqing Lemont IR64,and Kasalath; strains of *O. rufipogon* including 5948, 5949 , IRGC 105491, and BS7; several strains and cultivars of *Zea mays mays* including HouBai, Makkai, Min13, Pira, Sari, Smena, W22; several strains and cultivars of *Zea mays parviglumis*, including Benz, BK4, IA19, Wilkes; *Zea diploperennis*, and *Zea luxurians*. Furthermore, detailed description for each gene is provided (see pages 39-52). For example, Page 39, lines 12-27, describes the

characteristics of the EG307 gene in *O. sativa* (cv. Nipponbare) including the sequences of the 3' and 5' ends of the gene, the nucleotide ranges spanning the introns and exons in the gene, the sequence of the coding region, nucleotide ranges for stop and start codons, and the sequence of the protein sequence encoded by the gene. Page 52 further describes the structural relationship between the genes from various species, including high sequence identity among the various genes and subregions of genes, and common stop codon in the 5'UTR for rice.

According to the Written Description Guidelines, the "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." Applicant submits that the detailed reduction to practice for these known species of EG307 polynucleotides and polypeptides, combined with the exemplied and well-known methods for obtaining other species in the genus is adequate to describe the entire genus, and that Applicants are in possession of the genus of EG307 polypeptides and polynucleotides.

Reconsideration is respectfully requested.

The Rejection under 35 U.S.C. § 102(e)

The Examiner has rejected Claims 31-36, 45-47, 49, 50, and 53 under 35 U.S.C. § 102(e) as being anticipated by Chory, et al., U.S. Patent No. 6,245,969. The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *Alco Standard Corp. v. Tennessee Valley Auth.*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991) (citations omitted).

Specifically, the rejection reasons that Chory, et al., disclose a yield-related gene, and therefore can not be distinguished from "EG307" in the instant claims. The claims have been amended to refer to specific polynucleotides and polypeptides by reference to specific SEQ ID NO:'s. Chory, et al, does not disclose the recited SEQ ID NO:'s, and therefore cannot anticipate the present claims. Reconsideration is respectfully requested.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

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